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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/731,519	12/06/2000	R. David Rines		9558

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81 N. STATE STREET
CONCORD, NH 03301

EXAMINER

RIMELL, SAMUEL G

ART UNIT	PAPER NUMBER
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2165

DATE MAILED: 08/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/731,519

Applicant(s)

RINES, R. DAVID

Examiner

Sam Rimell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-11, 17-18, 21 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 6-11, 17-18, 21 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
- Paper No(s)/Mail Date ____.

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.


SAM RIMELL
PRIMARY EXAMINER

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-11, 17-18 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6: The phrase “the identical gene specific customized assay kits” lacks antecedent basis.

Claims 7-11, 17-18 and 21: Depend on claim 6.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-11, 17-18 and 21 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 6: Claim 6 has been amended to recite two features which are not found or otherwise suggested within the original disclosure. These are:

- (1) “identical gene specific customized assay kits”;
- (2) “whereby a positional shift of a spot in a new image spot pattern during such pattern overlay can be detected”.

The original disclosure does not appear to contain support for these features, and thus they are considered to be new matter.

Claims 7-11, 17-18 and 21: Depend from claim 6.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 6-11, 17-18 and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Bassett, Jr. et al. (U.S. Patent 6,453,241).

Claim 6: FIG. 6 discloses the generation of an image derived from the analysis of genes or proteins. The image is a pattern of spots. The pattern is gene specific (see FIG. 6 where the pattern is specific to a particular gene name). The image may be derived from a polymerase chain reaction that involves an electrophoresis separation, typically occurring a gel (col. 7, lines 61-65). A scanning device scans the image and stores the scan in a database (106). As seen in FIG. 1, multiple users (108, 116) can input the spot patterns into the database. Multiple users can retrieve the data from the database as well (col. 19, lines 16-17). The individual spot images are of standard size (FIG. 6) and follow a standard protocol for contrasting the spots (the spot is green or red, col. 4, lines 24-39). Col. 20, lines 22-39 outline the steps of taking individual spots and comparing them by the usage of data viewers.

Any equipment used in a laboratory to achieve the electrophoresis described at col. 7, lines 61-66 reads as a customized kit for identifying genes. Also note applicant's statement on page 7, line 10 of the specification, where applicant states: *"Apart from the resulting spot pattern images displayed on the gel, the details of such PCR-electrophoresis operations form no part of the novelty of the present invention."*

Claim 7: Electrophoresis equipment is customized for identifying genes. Without any description as to how the kit is customized, the claim reads on any electrophoresis equipment. Also not applicant's statement on page 7, line 10, of the specification.

Claim 8: Any electrophoresis equipment can be used for identifying unknown genes.

Claim 9: The image comparison permitted by the system of Bassett, Jr. et al. can assist in the identification of mutations (col. 42, lines 22-24).

Claim 10: The system of Bassett, Jr. et al. permits the evaluation of specific drug candidates on cells, thus aiding in identifying target cells affected by these drugs (col. 24, lines 60-62).

Claim 11: Col. 19, lines 13-21 describe the access of the database (or databases) by external researchers. Since the system is available over the Internet (112 in FIG. 1), the information in the databases has a global reach.

Claim 17: Col. 19, lines 13-21 describe the presence of other databases maintained by other research entities, which read as "protein databases", since they also contain the same biological response data as the database (106). The "biological response software" (304) reads as the "protein modeling software" since the biological response, such as the pattern of dots in FIG. 2, provides a visualization model of gene based or protein based materials.

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Claims 18: Col. 19, lines 13-21 describe other genomic references in the form of other research entities, “biological response software” that reads as “protein modeling software” and other databases (col. 19, line 14 in particular).

Claims 21: Each of the images are the same two dimensional color images. The images are thus standardized (they all have the same 2-D color format) and the standard dictates the size (two dimensions), position (within the two-dimensional image) and contrast (full color images).

Remarks

Applicant's arguments and amendments have been considered.

Applicant's arguments are primarily directed to the features set forth in the last six lines of claim 6. The features which have been amended to these lines of claim 6 are found to be new matter, and not found to have support in the original specification. With the exception of these new matter features, claim 6 has otherwise been written in independent form, utilizing the previously addressed limitations from claims 2 and 6.

Even if, for the sake of consideration, it were assumed that the features set forth in the last six lines of claim 6 were found to be supported, it is not believed that patentability could be established for these features. Applicant explicitly stated in the disclosure that the spot pattern images displayed in the gel and the details of the PCR electrophoresis operations form no part of the novelty of the present invention (page 7, line 10 of the specification). Given this assertion, it is not believed that patentability can be established by further claiming details of the spot pattern images or details of the PCR electrophoresis operations in claim 6.

This action follows a Request for Continued Examination and is made non-final.

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Any inquiry concerning this communication should be directed to Sam Rimell at telephone number (571) 272-4084.

A handwritten signature in black ink, appearing to read 'S. Rimell', is positioned above the printed name.

Sam Rimell
Primary Examiner
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